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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,465	06/22/2001	Edward B. Nelson	MCP-267	6932
27777	7590	04/08/2004	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			TRAVERS, RUSSELL S	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 04/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/887,465	NELSON ET AL.	
	Examiner	Art Unit	
	Russell Travers, J.D., Ph.D	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>1/15/04</u> . | 6) <input type="checkbox"/> Other: _____ |

The amendment and response filed January 15, 2004 have been received and entered into the file.

Applicant's arguments filed January 15, 2004 have been fully considered but they are not deemed to be persuasive.

Claims 1-18 are presented for examination.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 and 10-11 are rejected under 35 U.S.C. § 102(b) as being anticipated by Browner , of record.

Applicants' attention is directed to *Ex parte Novitski*, 26 USPQ2d 1389 (BOPA 1993) illustrating anticipation resulting from inherent use, absent a *haec verba* recitation for such utility. In the instant application, as in *Ex parte Novitski*, supra, the claims are directed to preventing a malady or disease with old and well known compounds or compositions. It is now well settled law that administering compounds inherently possessing a protective utility anticipates claims directed to such protective use. Arguments that such protective use is not set forth *haec verba* are not probative. Prior use for the same utility clearly anticipates such utility, absent limitations distancing the

proffered claims from the inherent anticipated use. Attempts to distance claims from anticipated utilities with specification limitations will not be successful. At page 1391, *Ex parte Novitski*, supra, the Board said "We are mindful that, during the patent examination, pending claims must be interpreted as broadly as their terms reasonably allow. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). As often stated by the CCPA, "we will not read into claims in pending applications limitations from the specification." *In re Winkhaus*, 52 F.2d 637, 188 USPQ 219 (CCPA 1975)". In the instant application, Applicants' failure to distance the proffered claims from the anticipated prophylactic utility, renders such claims anticipated by the prior inherent use. Although the instant claims recite treating arteriosclerosis, the therapeutic aim herein claimed is practiced by administration for any use. Absent limitations distancing this prior art inherent use the instant claims remain properly rejected as anticipated.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-2 and 10-11 are rejected under 35 U.S.C. § 103 as being unpatentable over Winokur in view of Mitchell et al, of record.

Winokur teaches COX-2 inhibitors as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. These medicaments are taught as useful for treating arteriosclerosis, viewed by the skilled artisan as the condition herein claimed. Claims 1-2 and 10-11 and the primary references, differ as to:

- 1) the failure to recite the specific COX-2 inhibitor as useful for the anti-atherosclerotic use herein claimed.

This failure is cured by Mitchell et al teaching the claimed acetaminophen as an old and well known inhibitor of cyclooxygenase enzymes, specifically COX-2. Possessing these teachings the skilled artisan would have been motivated to employ the COX-2 inhibitors taught by Mitchell et al for the instant use and have enjoyed a reasonable expectation of therapeutic success.

Claim 11 specifically require a defined dose. Winokur teaches employment of Cox-2 inhibitors, at a rate not exceeding 50 mg/kg, meeting the instant dosage rate. The skilled artisan would have seen all conventional compositions, and the

administration of these compositions by conventional means, at conventional physiological dosages, as residing in the skilled artisan purview.

Claims 3-9 and 12-18 are rejected under 35 U.S.C. § 103 as being unpatentable over Winokur in view of Mitchell et al as set forth for claims 1-2 and 10-11 above, in further view of Morehouse, Pick et al and Sun et al

Morehouse, Pick et al and Sun et al teach the acetaminophen, atorvastatin (claim 18), aspirin, vitamin C and vitamin E respectively as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. These medicaments are taught as useful for treating arteriosclerosis, viewed by the skilled artisan as the condition herein claimed. Claims 3-9 and 12-18, and the primary references, differ as to:

- 1) the concomitant employment of these medicaments.

It is generally considered prima facie obvious to combine two, or more, compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by the recited teachings, the instant claims define nothing more than the concomitant use of conventional anti-atherosclerosis agents. It would follow that the recited claims define prima facie obvious subject matter. Cf. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

RESPONSE TO ARGUMENTS

Examiner finds the rebuttal arguments unconvincing. Attention is directed to Mitchell et al (abstract and table 2) illustrating cyclooxygenase activity residing in the claimed acetaminophen. Simply stated, the Mitchell et al teaching fails to support the proffered argument. Note the rejection is based on the fact of inhibition, not relative inhibition as constructively averred. Absent information supporting the facts averred, the instant rebuttal arguments are unconvincing.

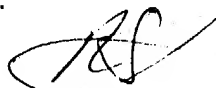
Examiner notes the instant claims read on prevention, yet those rebuttal arguments herein presented fail to support this utility. At page 8 of paper 12, Applicants set forth data residing in the instant specification. Attention is directed to the phrase "significantly reduced fatty streak deposits", setting forth a reduction in arteriosclerosis plaque formation, yet falling short of illustrating **prevention** of arteriosclerotic plaque formation herein envisioned and claimed. Simply stated, the instant specification fails to place the skilled artisan on possession of that regimen required to prevent the conditions herein envisioned, and claimed. Although the claimed subject matter may provide prophylactic benefits, the prevention benefit herein claimed is not illustrated, or suggested, in the instant application.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Travers, J.D., Ph.D whose telephone number is 703-308-4603. The examiner can normally be reached on Monday to Thursday from 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Russell Travers, J.D., Ph.D.
Primary Examiner
Art Unit 1617